

Application No. 10/510,435  
Amendment Dated 2/7/2007  
Reply to Office Action of November 30, 2006

**REMARKS/ARGUMENTS**

By this Amendment, claims 24-28 are amended. Claims 1-28 are pending. Cancellation of and/or amendment to the claims should in no way be construed as an acquiescence to any of the Examiner's rejections. The cancellation and/or amendments to the claims are being made solely to expedite prosecution of the instant application. Citations to the Specification are directed to U.S. Patent Application Publication No. 2005/0131067 (Parthasaradhi et al.).

Favorable reconsideration is respectfully requested in view of the foregoing amendments and the following remarks.

Claims 1-28 are pending in the instant application. In the Office Action of November 30, 2006, the Office Action summary listed that claim 1-18 were pending and rejected, while in the body of the Office Action, on page 2, the Examiner indicated that claim 1-28 are pending. Clarification is requested. Additionally, it is noted that claims 23-28 at least have been examined, as they were rejected. Additionally, claims 19-22 were not rejected under any grounds, and not addressed in the Office Action, and are presumed allowable.

**Rejections under 35 U.S.C. 112**

Claims 24-28 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is respectfully traversed.

The Examiner points out that Claim 24 depends on itself. In response, claim 24 has been amended to depend from claim 23. Reconsideration and withdrawal of the rejection is respectfully requested.

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Claims 25-28 stand rejected under 35 U.S.C. 112, fourth paragraph as not further limiting the claims from which they depend. This rejection is respectfully traversed.

The Examiner argues that Claims 25-28 claim forms other than the form claimed in claim 24. In response, the claims have been amended to depend from claim 23. Reconsideration and withdrawal of the rejection is respectfully requested.

**Rejections under 35 U.S.C. 102(b)**

Claims 1-4, 12-14, 16, 17, 23, 24, 27 and 28 stand rejected under 35 U.S.C. 102(b) as allegedly being anticipated by EP 0 325 571 (Jonsson et al.), and U.S. Patent No. 5,922,914 (Gage et al.). This rejection is respectfully traversed.

The Examiner argues that Jonsson et al. disclose mixing tolterodine with tartaric acid in ethanol followed by crystallization and further recrystallization from ethanol (s. example 12 and 22). The Examiner further argues that the '914 patent discloses disclose the production of tolterodine tartrate by reacting the free base with tartaric acid in ethanol followed by recrystallization, and that Applicants' products are not shown to be any different than the forms obtained by the cited references.

In Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987) (MPEP 2131), the CAFC set forth that "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference". In the instant case, not every element of the claims is present in the Jonsson reference or the '914 patent. The claims are drawn to specific crystalline forms of the product. Applicant submits that there is nothing in the cited references to show or

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suggest a product or process which produces a product with the specific x-ray powder diffraction spectrum as in the instant claims. As disclosed in the instant Specification, Applicants discovered that tolterodine tartrate can be prepared in four well-defined and consistently reproducible crystalline forms and one stable amorphous form (¶0005).

The Process disclosed in the instant Specification as producing Form II differs from the process in Examples 12 and 22 of the Jonsson reference, in that the reactions are performed for different times at different temperatures, and the Jonsson process requires seeding (Example 12) while the disclosed process does not. The process of the Jonsson reference would thus not be expected to produce the same polymorph.

Additionally, the process disclosed in the '914 patent also differs from the process as disclosed in the '914 patent (column 5, lines 10-43), as it is performed at different temperatures for different times, and the process of the instant Specification starts with tolterodine free base, while the '914 patent discloses starting with tolterodine hydrochloride. The process of the '914 patent would thus not be expected to produce the same polymorph.

The Examiner argues that Applicants' products are not shown to be any different than the forms obtained by the cited references, however, the instantly claimed products possess XRPD spectra which have not been shown by either the Jonsson reference or the '914 patent, and are prepared using different processes.

Accordingly, reconsideration and withdrawal of the rejection of claims 1-4, 12-14, 16, 17, 23, 24, 27 and 28 under 35 USC 102(b) is respectfully requested.

**Rejections under 35 U.S.C. 103(a)**

Claims 1-18 stand rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Jonsson et al., EP 0 325 571, and Gage et al., US 5,922,914, in view of Hawley et al., US 7,005,449. This rejection is respectfully traversed.

The Examiner admits that the instant invention differs from the teaching of the primary references in that not all solvents are disclosed and in that specific x-ray data are not given, and that additionally, spray drying, vacuum drying and freeze drying are not shown. The Examiner argues that Hawley et al. disclose at the top of col. 9 that "Crystallization was achieved using standard techniques known to a person skilled in the art" and that the use of various solvents and drying techniques to isolate and purify a product is within the purview of one of ordinary skill in the art.

The claims are patentable over the combination of the Jonsson reference and the '914 patent in view of the '449 patent for the following reasons. To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991), MPEP 2143.

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To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). MPEP 2143.03.

In the instant case, not every element of the claims is present in the combination of the references. The claims are drawn to specific crystalline forms of the product. Applicant submits that there is nothing in the cited references to show or suggest a product or process which produces a product, with the specific x-ray powder diffraction spectrum, as in the instant claims. Applicants discovered that tolterodine tartrate can be prepared in four well-defined and consistently reproducible crystalline forms and one stable amorphous form (¶0005). The process disclosed in the '914 patent, the Jonsson reference and the '449 patent differ from the process disclosed in the instant Application in time, temperature and starting materials. Therefore, the processes disclosed in the '914 patent, the Jonsson reference and the '449 patent would not be expected to yield the same polymorphic forms as instantly claimed.

The Examiner argues that Applicants' products are not shown to be any different than the forms obtained by the cited references, however, the instantly claimed products possess XRPD spectra which have not been shown by the combination of the Jonsson reference and the '914 patent, in view of the '449 patent.

Accordingly, reconsideration and withdrawal of the rejection of claims 1-18 under 35 U.S.C. 103(a) is respectfully requested.

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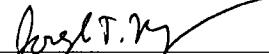
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For at least the reasons set forth above, it is respectfully submitted that the above-identified application is in condition for allowance. Favorable reconsideration and prompt allowance of the claims are respectfully requested.

Should the Examiner believe that anything further is desirable in order to place the application in even better condition for allowance, the Examiner is invited to contact Applicants' undersigned attorney at the telephone number listed below.

Respectfully submitted,

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February 7, 2007

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